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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,934	03/08/2002	Paul Averback	018792-0199	7362
22428 7590 08/22/2007 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER SANG, HONG	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/092,934

Applicant(s)

AVERBACK, PAUL

Examiner

Hong Sang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-52 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 48 is/are allowed.
- 6) ☒ Claim(s) 47, 59-51 and 55-59 is/are rejected.
- 7) ☒ Claim(s) 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Averbach

1. Applicant's response filed on 6/15/07 has been entered. Clams 47-52, and 55-59 are pending. New claims 55-59 are added. Claims 1-46 and 53-54 are cancelled. Claims 47, and 48 are amended.

2. Claim 47 which reads on SEQ ID NO.10 is free of the prior art. The search and examination of claim 47 is extended to the species "neural pancreatic thread protein. Due to applicant's species election of SEQ ID NO.10 (see 8/23/05 response), claims 52 is withdrawn from further consideration as being drawn to non-elected inventions.

...should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. See MPEP 803.02

3. Claims 47-51 and 55-59 are under examination.

Objections Withdrawn

4. The objection to claims 47-51 and 54 because claim 47 contains non-elected inventions i.e. unwanted hair, and a wart is withdrawn in view of applicant's amendment to the claims.

Response to Arguments

Claim Rejections - 35 USC § 112, 1st paragraph

5. The rejection of claims 47, 49-51 and new claim 55-59 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a benign tumor, a malignant tumor, hyperplasia, hypertrophy, overgrowth of a tissue and malformation of a tissue in a patient requiring removal or destruction of cells comprising locally administering (e.g. topically, intratumorally) to a mammal in need a therapeutically effective amount of the neural thread protein consisting of SEQ ID NO.10, does not reasonably provide enablement for a method of treating any and all conditions in a patient requiring removal or destruction of cells comprising systemically administering (e.g. intravenously, intra-arterially, intraperitoneally) to a mammal in need a therapeutically effective amount of any and all neural thread protein (NTP) as well as fragments, variant, derivative, homolog, reverse-D peptide, and enantiomers of NTP is maintained.

The response states that claims have been amended to treat the conditions selected from the group consisting of a tumor, hyperplasia, hypertrophy, and overgrowth of tissue and define the NTP as "SEQ ID NO.10, the protein identified by SEQ ID NO.2 to 9, neural pancreatic thread protein, or pancreatic thread protein. The response states that one skilled in the art can readily obtain the recited peptides, and the specification also teaches that exposing tissue to NTP kills the tissue, regardless of the type of tissues tested or its origin.

Applicant's arguments have been carefully considered but are not found persuasive. The amendment to claim 47 does not overcome the instant rejection. The claims as currently amended still encompass a method of treating a condition using a family of proteins that share homology or function similarities with neuronal thread proteins, as well as their biologically active fragments, variants, and derivatives, homologs, peptide mimetics, reverse-D peptides and entatiomers (see specification pages 9-11), also as evidenced by U.S. Patent No. 6,071,705 (Date of Patent: 6/6/2000). The specification defines "the neural pancreatic thread protein (nPTP) as proteins described in U.S. Patent No. 6,071,705 (see specification, page 11, lines 5-6). The US patent No. 6,071,705 explicitly teaches that the nPTP polypeptides include functional derivatives and fragments. While the instant specification teaches that local injection of SEQ ID NO.10 into tissue causes acute tissue necrosis at the injection site (see Example 2, page 45 of the specification), there is no indication that any other neural thread proteins, including neural pancreatic thread protein, and the fragments, derivatives, homologs, mimetics, and reverse-D peptides thereof are capable of inducing tissue necrosis. The specification does not disclose the core structural elements (such as a specific amino acid region or sequence) that are shared by the claimed proteins and such core structural elements are required by the genus of the NTP proteins to perform the claimed function. While it is understood that the absence of working examples should never be the sole reason for rejecting a claims as being broader than an enabling disclosure, the criticality of working examples in an unpredictable art is required for practice of the claimed invention. One cannot

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extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to a genus of proteins that share homology or function similarities with neuronal thread proteins, as well as their biologically active fragments, variants, and derivatives, homologs, peptide mimetics, reverse-D peptides and enantiomers, and applicant has not enabled any of these proteins, because it has not been shown that these proteins are capable of functioning as that which is being disclosed. As indicated in the previous office action, the prior art has demonstrated that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristics of a protein. Therefore, absent the evidence that any other NTPs except SEQ ID NO.10, can destroy or remove harmful or unwanted cells, one of skill in the art would not be able to predictably use any of these proteins and functional equivalents thereof for the destruction or removal of harmful or unwanted cells. Because of these reasons, the rejection is deemed proper and therefore, maintained.

Claim Rejections - 35 USC § 112, 1st paragraph

6. The rejection of claims 47, 49-51 and new claim 55-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response states that applicant has amended the claims to recite only NTPs for which the specification provides specific amino acid sequences. By providing the amino acid sequences, the specification provides a complete description of the recited NTPs.

Applicant's arguments have been carefully considered but are not found persuasive. The amendment to the claim 47 does not overcome the instant rejection. First of all, no specific SEQ ID NO is recited for the claimed "neural pancreatic thread protein" in the claim. The term "neural pancreatic thread protein" recited in the claims encompass a family of proteins that share homology or function similarities with neuronal thread proteins, as well as their biologically active fragments, variants, and derivatives, homologs, peptide mimetics, reverse-D peptides and entatiomers (see specification pages 9-11), also as evidenced by US Patent No. 6,071,705 (Date of Patent: 6/6/2000). The specification defines "the neural pancreatic thread protein (nPTP) as proteins described in U.S. Patent No. 6,071,705 (see specification, page 11, lines 5-6). The US patent No. 6,071,705 explicitly teaches that the nPTP polypeptides include functional derivatives and fragments. Because the claims as amended still encompass a method of treating a condition requiring removal or destruction of cells comprising administering fragments, homologs, variants, derivatives, mimetics, reverse-D peptides, and enantiomers of neural pancreatic thread protein, and the instant specification does not provide adequate support for all these modified proteins (see previous office action), the rejection is still deemed proper and therefore, maintained.

Double Patenting

7. The rejection of claims 47, 49-51 and new claims 55-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 of U.S. Patent No. 6,924,266B2 is maintained.

The response states that applicant encloses a terminal disclaimer disclaiming the term of any patent issuing from the present application that extends beyond the term of the '266 patent. The terminal disclaimer renders this rejection moot.

Because no terminal disclaimer was found in applicant's response, the rejection is maintained.

Double Patenting

8. The provisionally rejection of claims 1-7 and 9, and new claims 47, 49-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 and 18 of copending Application No. 10/294,891 and claims 9-13 and 15 of copending Application No. 10/920,313.

The response states that applicant will address the rejection on the merits if it ever matures into a non-provisional rejection.

Applicant's response is acknowledged. Since the applicant has not taken any actions, the rejection is therefore maintained.

Claim Rejections - 35 USC § 102

9. The rejection of claims 47, 49-51 and new claims 55, and 59 under 35 U.S.C. 102(e) as being anticipated by Xu et al. (US Patent No. 6,620,922B1, Date of Patent 9/16/2003, Filing Date: 8/9/2000) is maintained.

The response states that Xu cannot anticipate the claims because Xu does not teach the recited NTPs. More specifically, the claims no longer recite "fragments and variants of SEQ ID NO.10".

Applicant's arguments have been carefully considered but are not found persuasive. Because the term "neural pancreatic thread protein" encompass fragments and functional equivalents of a neural pancreatic thread protein (see above paragraphs 7 and 8), the polypeptide of SEQ ID NO.573 reads on the claimed neural pancreatic thread protein. Therefore, the rejection is deemed proper and maintained.

Conclusion

10. Claim 48 is objected to as being dependent from a rejected claim. Claims 47, 49-51 and 55-59 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Aug. 6, 2007

/Christopher Yaen/
Primary Examiner
Art Unit 1643
Aug. 21, 2007